REMARKS/ARGUMENTS

No amendment is made to any of claims 18-32. Claim 33 is cancelled. Claim 34 is newly added.

Support for claim 34, which recites that the active ingredient olanzapine or a pharmaceutically acceptable salt thereof is "uncoated", can be found at, for example, page 1, third paragraph, page 2, first full paragraph, paragraph bridging pages 2-3, page 3, last paragraph, and page 9-10, Examples of the originally filed specification. Specifically, at page 1, third paragraph, the specification discusses various problems of the prior art, including the requirement for sub-coating and coating to assure the protection of the active substance from moisture and light. At page 2, first full paragraph, the specification discloses that EP 0733367B1 requires the steps of sub-coating and coating to avoid a direct contact of the active ingredient olanzapine with other inactive ingredients, such as polyethylene glycol. At the paragraph bridging pages 2-3, the specification discloses that EP 0830858A1 (recited herein by the Examiner as the primary reference) emphasizes the coating of the active ingredient to ensure uniform physical stability and prevent the undesired discoloration. At page 3, last paragraph, the specification discloses:

> It was surprisingly found by the present inventors that stable pharmaceutical formulations comprising olanzapine as the active ingredient, which do not show any undesired discoloration and have an excellent dose uniformity, can be prepared by a simple direct compression process if olanzapine or a pharmaceutically acceptable salt thereof is first homogeneously mixed with certain excipients and then subjected to direct compression. The direct compression is preferably performed in the absence of any solvent. In view of the fact that the excipients used by the present inventors are commonly used for manufacturing tablets, the finding that they allow the production of stable olanzapine formulations without any need for a coating or wet granulation was totally unexpected.

(Emphasis added.)

Then at pages 9-10, Examples 1-3, olanzapine is "uncoated" in every composition illustated therein.

Therefore, the orginally filed specification of the present application has reaonably conveyed to a person of ordinary skill in the art that the inventors had the possession of a formulation comprising "uncoated" olanzapine or pharamaceutially acceptbale salt thereof. *See*, e.g., MPEP 2163.02. Accordingly, new claim 34 is supported by the orginally filed specification.

In view of the foregoing, Applicants respectfully request that the above amendments to the claims be entered. Upon entry of the above amendments, claims 18-32 and 34-35 are pending. Reconconsideration of the present application in view of the above amendments and the following remarks is respectfully solicited.

1. Claim Rejections under 35 U.S.C. § 102

Claims 18-28 and 31-32 are rejected 35 U.S.C §102(b) as being anticipated by Morris et al. (EP 0 830 858 A1) as evidenced by Nakajima et al. (U.S. 3,926,817). Applicants respectfully traverse.

Independent claim 18 recites a pharmaceutical formulation comprising olanzapine or a pharmaceutically acceptable salt thereof as an active ingredient, produced by homogeneously mixing (a) olanzapine or a pharmaceutically acceptable salt thereof with (b) a monosaccharide and/or oligosaccharide and/or a reduced or oxidised form thereof, (c) a polysaccharide and optionally one or more additional excipients, followed by a direct compression of the mixture into tablets in the absence of any solvent. In other words, the pharmaceutical formulation is a homogenous mixture of olanzapine and polysaccharide, monosaccharide and/or oligosaccharide, etc. As evident from the specification, such a homogenous mixture is different from the

olanzapine formulation, which is prepared by coating the active ingredients or granulation, etc., and therefore is not a homogenous mixture.

For example, in Morris cited herein by the Examiner, the active ingredient olanzapine must first be coated with other ingredients, before being mixed with lactose and celluloses, which seem to be recognized by the Examiner as the monosaccharide and/or oligosaccharide, and polysaccharide recited in claim 18. In other words, Morris fails to disclose a homogeneous mixture comprising (a) olanzapine or a pharmaceutically acceptable salt thereof; (b) a monosaccharide and/or oligosaccharide and/or a reduced or oxidised form thereof, and (c) a polysaccharide, as recited in claim 18.

Another reference, Nakajima, is merely relied upon by the Examiner to show that magnesium stearate is a known glidant in the art. It cannot remedy any deficiency discussed above in connection with Morris.

Therefore, claim 18 is not anticipated under 35 U.S.C. § 102(b) by Morris, as evidenced by Nakajima. For at least the same reasons, claims 19-32, which all depend from claim 18, are also not anticipated by Morris under 35 U.S.C. § 102(b). Withdrawal of rejections of claim 18-28 and 31-32 in view of Morris, as evidenced by Nakajima, under 35 U.S.C §102(b) is, therefore, respectfully requested.

Note that in the International Preliminary Examination Report of the corresponding PCT application, the PCT Examination Authority has recognized that the claims in the PCT application, which are substantially similar to the claims of the present application, are novel and comprise an inventive step in view of Morris. Similarly, the European Patent Office has granted the corresponding European application, which contained substantially similar claims as does the present application, even though a Third Party Observation citing Morris as one of the primary

reference was submitted to the European Patent Office during the prosecution. These related proceedings further support Applicants' above remarks regarding the distinction of the formulation described in claim 18 and the Morris formulation.

Similarly, new claim 34 also recites a homogeneous mixture comprising (a) olanzapine or a pharmaceutically acceptable salt thereof; (b) a monosaccharide and/or oligosaccharide and/or a reduced or oxidised form thereof, and (c) a polysaccharide. Therefore, the remarks discussed above in connection with claim 18 also apply equally to claim 34.

Moreover, claim 34 recites that the active ingredient olanzapine or a pharmaceutically acceptable salt thereof is "uncoated." In contrast, according to the teachings of Morris, olanzapine must be coated to prevent discoloration. This provides a further ground that claim 34 is patentable over Morris.

2. Claim Rejections under 35 U.S.C. § 103

Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Morris, as evidenced by Nakajima. The Examiner recognizes that the amounts of several ingredients recited in claims 29-30 are not disclosed by the cited art but concludes that the amounts recited in claims 29-30 would have been obvious in the absence of the showing of criticality of the recited amount. Regardless of whether the Examiner's statement is correct, as noted above, Morris in combination with Nakajima fail to disclose all of the limitations of claim 18, from which claims 29-30 depend as discussed above. Therefore, claims 29-30 are not obvious under 35 U.S.C. §103(a) over Morris as evidenced by Nakajima. Withdrawal of the rejections of claims 29-30 is respectfully requested.

It is believed that no additional fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
COHEN PONTANI LIEBERMAN & PAVANE LLP

By /Kent H Cheng/

Kent H. Cheng
Reg. No. 33,849
551 Fifth Avenue, Suite 1210
New York, New York 10176
(212) 687-2770

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